REMARKS

Claims 581-599, 601-612, 614-621, 623-639 and 674-695 are pending currently. Claims 581-596 are directed to a composition comprising particulate apatite having an average apatite particle size of less than 1 μm, an average apatite crystal size of less than 150 nm, and a surface area of at least 40 m^2/g. Claims 597-599, 601-612, and 614-619 are directed to an article comprising a densified apatite structure having a dimension of at least about 0.5 cm and an average XRD crystal size of less than 250 nm, wherein the apatite structure undergoes phase decomposition of less than 10% when exposed to conditions of at least 1300 °C for at least 2 hours and has a compressive strength of at least about 150 MPa. Claims 620, 621, and 623-639 are directed to an article comprising an apatite structure having a dimension of at least 0.5 cm, a density of at least 98%, a compressive strength of at least about 500 MPa, and an average XRD crystal size of less than 250 nm. Claims 674-695 are directed to an article comprising a consolidated apatite structure having a dimension of at least about 0.5 cm, an average XRD crystal size of less than 250 nm, and a porosity of at least 20%, wherein the apatite structure undergoes phase decomposition of less than 10% when exposed to conditions of at least 1300 °C for at least 2 hours. Reconsideration of the pending claims is respectfully requested.

The Amendments to the Claims

Claims 581-583, 597, 603, 604, 620, 621, and 625 have been amended to delete the term "about." Claim 595 has been amended to recite that the particulate apatite is admixed with an organic species, as supported by the specification at col. 10, lines 36-50. Claim 597 has been amended to recite that the densified apatite article has a compressive strength of at least about 150 MPa thereby incorporating the feature of claim 601. Claim 600 has been canceled. Claims 601 and 602 have been amended to recite that the apatite structure has a compressive strength of about 500 MPa and about 700 MPa, respectively, as supported in the specification at col. 11, lines 51-57. Claim 613 has been canceled. Claims 614, 615, 626, and 627 have been amended to correct the misspelled term "prosthesis". Claim 620 has been amended to delete the duplicate term "having" and to recite that the apatite structure has a compressive strength of at least about 500 MPa, thereby incorporating the feature of claim 622. Accordingly, claim 622 has been canceled. Claim 623 has been amended to recite that the apatite structure has a compressive strength of about 700 MPa as supported in the specification at col. 11, lines 51-57. Claims 640-673 have been canceled as being directed to a non-elected invention.

New claims 674-695 have been added. Newly added claims 674-695 recite a consolidated apatite structure having a dimension of at least 0.5 cm, an average XRD crystal

size of less than 250 nm, and a porosity of at least 20%, wherein the apatite structure undergoes phase decomposition of less than 10% when exposed to conditions of at least 1300 °C for at least 2 hours. Newly added claim 674 is similar to claim 597 except that the claim recites a consolidated apatite structure instead of a densified apatite structure and recites a porosity of at least 20%. Support for "consolidated particulate apatite" can be found in the instant specification at col. 11, lines 59-65. Support for the recitation of porosity in claims 674-676 can be found in the instant specification at col. 11, lines 46-51. Newly added claims 677-688 are the same as claims 601, 603-612. Newly added claims 691-695 are the same as claims 614-619. Newly added claim 689 is similar to canceled claim 613 but recites a solidified apatite structure prepared from an admixture of particulate apatite and an organic species. Newly added claim 690 recites that the organic species is a self-assembling surfactant or polymer. Newly added claims 689 and 691 are supported in the specification at col. 10, lines 36-50.

No new matter has been added by way of any of these amendments.

Summary of the Office Action

Claims 640-673 are withdrawn from consideration as being directed to a non-elected invention. Claims 581-639 stand rejected under 35 U.S.C. § 251 for improper recapture. Claims 581-583, 595, 596, and 613 stand rejected under 35 U.S.C. § 251 as being based upon new matter and under 35 U.S.C. § 112, first paragraph, as containing subject matter not described in the specification. Claims 612, 617, 618, 629, 630, and 638 stand rejected under 35 U.S.C. § 112, first paragraph, for lacking enablement. Claims 581-596 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claims 581, 584, and 585 stand rejected under 35 U.S.C. § 102(b) as anticipated by Aldrich (i.e., the Aldrich composition described in Table 2, Example 2, of the instant specification). Claims 581-586 stand rejected under 35 U.S.C. § 102(b) as anticipated by Niwa et al. (i.e., U.S. Patent 4,497,075 or U.S. Patent 4,429,691) (incorrectly referred to as Nagai in the Office Action). Claim 586 stands rejected under 35 U.S.C. § 103(a) as obvious over Aldrich. Claims 620, 622, 623, and 626-630 stand rejected under 35 U.S.C. § 103(a) as obvious over Jarcho (i.e., U.S. Patent 4,097,935).

Preliminary Amendment

The Office Action objects to the preliminary amendment filed May 31, 2002 as containing newly added claims that were not properly underlined, as is required by 37 C.F.R. § 1.173(b). A supplemental paper is filed herewith correctly underlining the newly added claims of the reissue application, as requested by the Office.

Information Disclosure Statement

The Office Action indicates that the Information Disclosure Statement filed June 3, 2002 contains starred references that have been considered but were lined out to prevent confusion with the printer. The PTO-1440 form is resubmitted herewith but without stars, as requested by the Office. The Examiner is respectfully requested to initial these references and formally acknowledge that they have been considered.

Restriction Requirement

The Office Action indicates that claims 640-673 are withdrawn from consideration as being directed to a non-elected invention. Accordingly, claims 640-673 have been cancelled. Applicants reserve the right to pursue these non-elected claims in a divisional application.

Discussion of Improper Recapture

The rejection of claims 581-639 under 35 U.S.C. § 251 for allegedly improper recapture is respectfully traversed. Applicants maintain that (1) the narrow scope of the original patent claims was made in error without deceptive intent and that (2) the instant claims do not improperly recapture previously surrendered subject matter as alleged in the Office Action.

A. The Original Patent Prosecution

The application for patent originally contained claims reciting a composition of particulate apatite that was limited only by the average apatite crystal size (i.e., less than 250 nm). During prosecution, the claim was amended to recite "a composition, as precipitated comprising particular apatite having an average apatite crystal size of less than ~~250~~ 100 nm, wherein the crystal is spherical." Thus, the claim was narrowed with respect to the crystal size and crystal shape for an "as precipitated" composition. As a result of an Examiner interview, during which the Examiner noted that the specification did not support the formation of spherical crystals "as precipitated" but only taught the formation of spherical crystals after aging, the "as precipitated" limitation was removed from the claims by Examiner's amendment.

B. The Pending Claims

The current claims, though broader in that they do not limit the average crystal size to less than 100 nm and the crystal shape to spherical, are considerably narrower in that they recite a limitation for the average apatite particle size of less than 1 μm, which limitation was not present in the previously canceled claim. The average particle size is not the same as the average crystal size. A particle is made up of one or more individual crystals that typically

are agglomerated together. The average particle size thus will be larger than the average crystal size, except in the atypical case where crystal agglomeration is absent. The present invention is directed to a particulate apatite having an average particle size that approaches the average crystal size. Accordingly, the instant claims are not of the same scope as those previously canceled. Rather, the instant claims are of intermediate scope (i.e., they are broader than the claims of the original patent yet narrower than the canceled claims) since the claims contain an additional limitation not present in the previously canceled claims.

C. Error Without Deceptive Intent

The amendment to the original claims to include the limitations of less than 100 nm average crystal size and a spherical crystal shape was made in error and without deceptive intent within the meaning of 35 U.S.C. § 251. The average crystal size and spherical limitations unduly limit the scope of the claims such that they cover significantly less than that which the Applicants are entitled.

It is well settled that a claim can be intentionally and deliberately amended in error. See, for example, In re Richman, 161 USPQ 359 (CCPA 1969), which states:

> "Certainly one might err without deceptive intention in adding a particular limitation where a less specific limitation regarding the same feature, or an added limitation relative to another element, would have been sufficient to render claims patentable over prior art."

Similarly, In re Wadlinger, Kerr, and Rosinski, 181 USPQ 826 (CCPA 1974), which found that there could be 'error' within meaning of 35 U.S.C. 251, although cancelled claims in the original application and claims in reissue application were directed to the same process, where the scope of the abandoned claims was broader than the scope of the reissue claims.

In the instant case, the spherical limitation was not the only limitation that could have been added to the claim to secure issuance. Rather, a less specific limitation regarding the average particle size of the particulate apatite would have been sufficient to overcome the prior art rejections.

D. Improper Recapture

The recapture rule seeks to prevent an Applicant from claiming subject matter that was previously surrendered. Two factual determinations have been set forth for determining the propriety of the recapture doctrine: 1) Are the reissue claims substantially identical to the abandoned claims? and 2) Were the critical limitations added or withdrawn at the insistence of the Patent Office? Both questions are required to be answered in the affirmative before the recapture doctrine can be properly applied. *See* Tee-Pak, Inc. v. St. Regis Paper Company, 181 USPQ 75 (CA 6 1974). In the instant case, the reissue claims are not substantially

identical to the abandoned claims. Rather, the reissue claims contain a significant additional limitation that was not present in the abandoned claims, namely the requirement that the particulate apatite composition have an average particle size of less than 1 μm. Thus, Applicants are not attempting to recapture the same or an immaterially different subject matter from that previously abandoned since the reissue claims are of a different scope than those previously abandoned.

In view of the foregoing, the rejection under U.S.C. § 251 is improper and should be withdrawn.

Discussion Of New Matter Rejection

The rejections of claims 581-583, 595, 596, and 613 under 35 U.S.C. §§ 251 and 112, first paragraph, are moot in view of the amendments to the claims. The term "about" has been deleted from the claims. Claim 595 has been amended to recite that the particulate apatite is "admixed with the organic species," reflecting the language of the specification. Claim 613 has been cancelled. Accordingly, the rejections under 35 U.S.C. §§ 251 and 112, first paragraph, should be withdrawn.

Discussion Of Enablement Rejection Of Claims 617, 618, 629, And 630

The rejection of claims 617, 618, 629, and 630 is respectfully traversed. Claims 617 and 629 each recite a bioactive implant. The Office offers no explanation or support for its rejection of these claims. Claims 618 and 630, which recite orthopedic and dental implants, are dependent on claims 617 and 629, respectively. With respect to these claims, the Office alleges that the instant specification does not enable one of ordinary skill in the art to make any type of dental or orthopedic implant, but only enables load-bearing implants as taught at col. 9, lines 64-65. The Office offers no support for its assertion that these claims are not enabled.

Contrary to the Office Action, the instant specification makes it clear that the apatite composition recited in the pending claims can be used to produce prosthetic implants or coatings for prosthetic implants (see, e.g., the Abstract). Additionally, the background of the instant specification teaches that the use of hydroxyapatite in implants was commonly known in the art at the time of the invention, as were methods of preparing implants. The specification discusses that conventional hydroxyapatite compositions can be used to prepare powders, "unloaded" implants, implant coatings, or implants having reinforcing metal posts (see, e.g., col. 4, beginning line 7), but that the limits of these conventional hydroxyapatite articles have prevented their use in load-bearing applications. In particular, the specification states that hydroxyapatite is "an attractive and widely utilized bioceramic material for

orthopedic and dental implants" (see col. 3, lines 30-34). The inventive apatite composition and article disclosed and claimed by the Applicants attempt to solve the problems of these conventional apatite articles. The inventive apatite articles are suitable for use not only in unloaded implants, but also as load-bearing implants due to the improvement in density and mechanical strength. The instant specification does not exclude the use of the inventive hydroxyapatite composition in unloaded implants, but merely highlights the additional possibility of their use in load-bearing implants. One of ordinary skill in the art would readily recognize that an apatite article suitable for use in load-bearing applications could also be used in unloaded applications. Although there are no specific examples illustrating the use of the apatite composition of the invention in a non-load bearing implant, the Office is reminded that "[c]ompliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." M.P.E.P. §2164.02.

Since the Office has not provided any evidence as to why the instant specification is not considered to enable one of skill in the art to prepare unloaded implants in addition to load-bearing implants, and in view of the fact that the specification clearly teaches that the apatite composition of the invention can be used to prepare implants or coatings for implants including unloaded and loaded implants, the enablement rejection is improper and should be withdrawn.

Discussion Of Enablement Rejection Of Claims 612 And 638

The rejection of claims 612 and 638 is respectfully traversed. The Office alleges that the instant specification does not enable one of ordinary skill in the art to make any article comprising densified carbonate apatite, but only enables implants having a reactive layer of nanocrystalline carbonate apatite citing Example 12. The Office provides no evidence to support its contention that one of ordinary skill in the art would be unable to prepare an article comprising densified carbonate apatite.

The specification clearly teaches that the processes used to produce particulate hydroxyapatite, densified hydroxyapatite, and articles of hydroxyapatite can also be used to produce carbonate apatite stating that "carbonate ions can be substituted for phosphate ions in hydroxyapatite to yield carbonate apatite" (see col. 6, lines 4-9) and that using the wet chemical processing, a variety of products including hydroxyapatite, carbonate apatite, and fluoroapatite in the form of nanocrystalline dense structures as well as high surface area powders and coatings are developed" (see, e.g., col. 6, lines 4-9). Example 12 illustrates how the hydroxyapatite process can be modified to produce carbonate apatite. However, while the example happens to discuss the formation of carbonate apatite for use in a coating, the

example is not intended to suggest that carbonate apatite can only be used to prepare an implant coating.

Absent any evidence as to why one of ordinary skill in the art would be unable to prepare an article of densified carbonated apatite as recited in the pending claims, and in view of the fact that the specification clearly teaches that carbonated apatite articles can be prepared by simple substitution of carbonate ions for phosphate ions as illustrated by Example 12, the enablement rejection is improper and should be withdrawn.

Discussion Of Indefiniteness Rejection

The rejection of claims 581-596 as allegedly indefinite is moot in view of the amendments to the claims to delete the term "about."

Discussion Of Anticipation Rejections

The anticipation rejections over Aldrich and Niwa (incorrectly referred to as Nagai et al. in the Office Action) are respectfully traversed.

The pending claims recite a composition comprising particulate apatite having (a) an average apatite particle size of less than 1 μm, (b) an average apatite crystal size of less than 250 nm, and (c) a surface area of at least 40 m^2/g. As discussed previously, the average particle size is not the same as the average crystal size. A particle is made up of one or more individual crystals that typically are agglomerated together. The average particle size thus will be larger than the average crystal size, except in the atypical case where crystal agglomeration is absent. The present invention is directed to a particulate apatite having an average particle size that approaches the average crystal size. Neither of the cited references discloses a particulate apatite composition having an average apatite particle size of less than 1 μm as is recited in the pending claims.

The Aldrich hydroxyapatite composition listed in Table 2 of Example 2 identifies the average crystal size and surface area of the composition; and these are within the range recited in the pending claims. However, the average particle size is not set forth. Tests on recent Aldrich samples show that the average particle size is not less than 1 μm and thus would not be within the scope of the pending claims. Indeed, the average particle size is about 15 μm, well above the range recited in the pending claims. Based upon information from Aldrich, it is understood that no change has been made that would have affected to any appreciable extent the average particle size of the Aldrich composition sample that was referred in Example 2. Applicants stand ready to provide this information in a Declaration if the Office considers that this is necessary.

However, it is clear from the record that a small average apatite crystal size does not equate to a small average apatite particle size. Thus, though Niwa et al. disclose a particulate apatite composition having an average crystal size within the claimed range, Niwa et al. disclose that the hydroxyapatite has a particle size of *300 μm or less* (see, e.g., Niwa et al., the '691 patent, at col. 4, lines 37-41). Nothing in Niwa et al. teaches or suggests the desirability of a hydroxyapatite composition having an average particle size that approaches the average crystal size set forth in the pending claims, or, in particular, an apatite composition having an average particle size of *less than 1 μm*.

Since neither the Aldrich composition nor Niwa et al. disclose a hydroxyapatite composition having an average particle size of less than 1μm as is required by the pending claims, the anticipation rejections are improper and should be withdrawn.

Discussion Of Obviousness Rejections

The obviousness rejection of claim 586 over Aldrich is respectfully traversed. As discussed above with respect to the anticipation rejection, there is no basis to conclude that the Aldrich composition has particles with an average particle size of less than 1 μm as is required by the claim, and no evidence has been presented of motivation to carry out any process that could lead to modification of the Aldrich composition in a way that could result in the subject matter of claim 586, with a reasonable expectation of success. Accordingly, the obviousness rejection over Aldrich is improper and should be withdrawn.

The obviousness rejection of claims 620, 622, 623, and 626-630 over Jarcho is respectfully traversed. Independent claim 620 recites an article comprising an apatite structure having a dimension of at least 0.5 cm, a density of at least about 98%, a compressive strength of at least about 500 MPa, and an average XRD crystal size of less than 250 nm. Jarcho discloses densified hydroxyapatite having an average crystallite size in the broad range of 0.2 to 3 μm (200 to 3000 nm) (see col. 5, line 13); however, there is not a single example of an apatite composition having an average crystallite size less than 250 nm as is recited in the pending claims. Rather, Example 3 discloses a *crystallite size distribution* of 0.7 to 3 μm (700 nm to 3000 nm) (see col. 20, lines 47-48), which would clearly have an *average crystal size* far above the range of less than 250 nm recited in the pending claims. Indeed, the lower limit (i.e., 700 nm) of the size distribution range of the material of Example 3 is almost three times the value for the upper limit (i.e., 250 nm) of the average crystal size recited in the pending claims. Absent any teaching or even recognition of the importance of having an average crystal size less than 250 nm, Jarcho cannot properly be considered to render the claim obvious. Accordingly, the obviousness rejection is improper and should be withdrawn.

Patentability Of Newly Added Claims

Newly added claims 674-695 are patentable over each of the cited references. Specifically, the Aldrich composition is a powder and not a consolidated apatite article. Niwa et al. does not teach or suggest a consolidated apatite article having a dimension of at least 0.5 cm and an average XRD crystal size of less than 250 nm, wherein the structure undergoes phase decomposition of less than 10% when exposed to conditions of at least 1300 °C for at least 2 hours. Applicants note that newly added independent claim 674 is similar to independent claim 597, which was not subject to any art rejections under Sections 102 or 103.

Conclusion

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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